DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-669/S-021, S-022, S-023

Glaxo Wellcome, Inc
Five Moore Drive
PO Box 13398
Research Triangle Park, NC 27709-3398

Attention: Kevin C. Fitzgerald, R.Ph.
Senior Assistant Director
Technical Regulatory Affairs

Dear Mr. Fitzgerald:

Please refer to your supplemental new drug applications dated April 12, 2001, received April 13, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Leukeran (chlorambucil) 2 mg Tablets.

We acknowledge receipt of your submissions dated March 6 and April 12, 2001. Your submission of April 12, 2001 constituted a complete response to our March 12, 2001 action letter.

These supplements provide for a manufacturing site change for both the Drug Substance and the Drug Product, a reformulation, and labeling change.

We have completed the review of these supplemental applications, and they are approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21CFR 314.80 and 314.81.

If you have any questions, call Maureen Pelosi, Project Manager, at (301) 594-5778.

Sincerely,

{See appended electronic signature page}
Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur
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